

Message

From: Vandenberg, John [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCAE2B98A04540FB8D099F9D4DEAD690-VANDENBERG, JOHN]
Sent: 2/21/2019 4:08:34 PM
To: Bahadori, Tina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7da7967dcafb4c5bbc39c666fee31ec3-Bahadori, Tina]; Thayer, Kris [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3ce4ae3f107749c6815f243260df98c3-Thayer, Kri]
Subject: FW: advice please #2

Ok - sent

From: Vandenberg, John
Sent: Thursday, February 21, 2019 11:08 AM
To: Vandenberg, John <Vandenberg.John@epa.gov>
Subject: RE: advice please #2

Hi Dick,

Deliberative Process / Ex. 5

Best,
John

From: Vandenberg, John
Sent: Thursday, February 21, 2019 8:26 AM
To: Personal Matters / Ex. 6
Subject: RE: advice please

Hi Dick,

Thanks for your note. As noted in the article below, the EPA recently announced the IRIS assessment priorities. The IRIS manganese assessment has been suspended for FY19 since it was not identified as a top priority by the EPA program offices. Should the priority needs change, IRIS will move forward with the draft assessment. The IRIS website will be updated shortly with information on status of the assessments, so I suggest looking at that site occasionally for updates.

Best,
John

From: Personal Matters / Ex. 6
Sent: Wednesday, February 20, 2019 11:46 AM
To: Vandenberg, John <Vandenberg.John@epa.gov>
Subject: advice please

John

I hope all is well with you. I am still doing a bit of consulting although semi retired.

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As you may remember, one of my clients is Afton Chemical who did a lot of work with EPA ORD folks re manganese research and they have remained interested in possible IRIS review of manganese.

I thought manganese was on the IRIS priority list for review soon and had heard EPA staff had started initial efforts but the noticed the article below re the EPA program outlook which does not mention manganese.

I would appreciate any update you could give me on what the status is re a review of the IRIS manganese levels. I noticed that EPA in the residual risk assessment for coal and oil fired EGU source category again relied on the ATSDR MRL vs the EPA IRIS one.

Thanks so much and all the best

Dick Wilson

Personal Matters / Ex. 6

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Personal Phone / Ex. 6 | cell

EPA Scales Back IRIS Assessment Schedule, Creating New Uncertainties

December 19, 2018

Following a high-level review, EPA has released a scaled-back agenda of chemicals that its Integrated Risk Information System (IRIS) program will assess over the next few years, providing some certainty after months of limited public activity.

But the plan appears to create new uncertainties as there is no mention of formaldehyde, an assessment Democrats are demanding be released, and several pending assessments lack milestones.

EPA Dec. 19 released a "Program Outlook" for IRIS, describing "assessments that are currently in development and their projected public milestones," according to an email from the program.

The list contains some 13 chemicals or groups of chemicals at various stages of assessment, including likely controversial assessments of toxic or hazardous substances, such as arsenic, hexavalent chromium (Cr6), polychlorinated biphenyls (PCBs), methylmercury and related compounds, and five perfluorinated chemicals.

The list appears to put the IRIS program -- which assesses the hazards of substances -- on a somewhat firmer footing in the face of calls to eliminate it by many industry and GOP critics, who charge its assessments are too conservative and drive overly stringent standards.

But the new agenda provides anticipated release dates for various steps in the development of only five of the assessments, while the remaining eight are listed as "to be determined."

EPA appeared to downplay any potential uncertainties about the program's schedule. "These assessments have been identified as high priority needs of the Agency for fiscal year 2019. The anticipated dates of the IRIS activities communicated in this update are based on several factors, including complexity of the assessment products and the availability of resources," the agency said.

The list is significantly scaled back from an agenda the program released in 2015, when the agency said it was assessing 22 substances, and listed 15 more as being of high priority to begin assessment.

Noticeably absent from the current list is any indication that the agency is continuing work on its draft assessment of formaldehyde, which several Democratic senators accuse the Trump EPA of blocking from public release.

Sens. Ed Markey (D-MA), Sheldon Whitehouse (D-RI) and Tom Carper (D-DE), ranking member of the Environment and Public Works Committee, wrote former Administrator Scott Pruitt last May, urging him to release the assessment. In the letter, they charged that the draft had been completed more than a year ago, and that industry groups were pressuring the Trump EPA not to release it because it links formaldehyde exposure to leukemia. More recently, Markey and others have sought commitments from EPA to release the document in association with the pending confirmation of EPA nominees, including Alexandra Dunn, President Donald Trump's nominee to head EPA's toxics office, and Peter Wright, the nominee to lead EPA's waste office.

Wheeler's Review

Acting Administrator Andrew Wheeler told reporters last summer that he would release the formaldehyde assessment once he had completed a review of it to ensure its accuracy as well as a broader review of the IRIS program's agenda and whether it is adequately serving regulatory programs.

"What I have asked the IRIS program is that we need to make sure we have identified the customer for analysis," Wheeler told reporters. "And we need to know what the end result of the product will be, and what the regulatory process" is, "not just for formaldehyde but for all the IRIS assessments," he said.

Wheeler's review appeared to stall the program's public activities for months. While that broader review now appears to be complete, the formaldehyde assessment remains in limbo. Markey has signaled that he anticipates Wright will be confirmed without EPA committing to the assessment's release; it is unclear if Democrats will be able to secure commitments related to Dunn or Wheeler's nominations.

The outlook document indicates that two IRIS assessments, of ethyl tertiary butyl ether (ETBE) and tert-Butyl Alcohol are at the peer review stage, but does not provide an estimate of when the documents will be finalized.

EPA's Science Advisory Board subcommittee on chemical assessments met for a public peer review of the two draft chemical assessments in August 2017. At the time, the panel appeared to have some split conclusions, which could complicate EPA's ability to address the panel's recommendations. A footnote on the outlook explains, "[u]pon receipt of the final external peer review report, the IRIS Program will update Table 1 with the projected date for the next public milestone."

The outlook describes eight chemicals in the "draft development" stage, including arsenic, Cr6, PCBs, and five per- and polyfluoroalkyl substances (PFAS): perfluorononanoic acid (PFNA), perfluorobutanoic acid (PFBA), perfluorohexanoic acid (PFHxA), perfluorohexane sulfonate (PFHxS) and perfluorodecanoic acid (PFDA).

The PFAS assessments "under development are in support of EPA's Actions to Address PFAS."

The IRIS program indicates that its public comment draft for the arsenic assessment will be completed in the second quarter of fiscal year 2020; for the Cr6 assessment in the first quarter of FY20 and for the PCB assessment the first quarter of FY21.

The three are perhaps surprising picks, considering their complexity and controversy. EPA in that past has tried to update existing IRIS assessments of arsenic and Cr6, but in each case was met with strong pushback from regulated entities fearful of strict and expensive regulations, as well as scientific controversies related to how to assess human health risks at low doses of exposure.

Scoping & Problem Formulation

The outlook lists three chemicals that are in the "Scoping and Problem Formulation" stage of development: mercury salts, methylmercury and vanadium and compounds." The outlook anticipates a public comment draft for the mercury salts assessment will be completed in the fourth quarter of FY20 and a draft for the methylmercury assessment in the second quarter of FY21. Vanadium's schedule is to be determined.

"The anticipated dates are based on several factors, including complexity of the assessment products and the availability of resources," the outlook states. "While projected dates reflect the IRIS Program's best estimate based on available information, they are subject to change."

The PFAS chemicals are the only chemicals new to IRIS' agenda from 2015, also a multi-month development project that sought to gather intra-agency input on programs' priorities to develop the agenda.

When new staff took over the IRIS program in early 2017, they sought to re-evaluate the 2015 agenda, describing it at one public meeting as overly ambitious for the resources available to the program.

The vanadium compounds assessment is an interesting choice, as the agency program several years ago came close to finalizing an assessment of vanadium pentoxide (V2O5) rather than all of the related compounds.

The IRIS program in its fiscal year 2015 budget request had said the V2O5 assessment was "anticipated to be complete in early 2015," but industry and the defense department in 2014 sought a second peer review of a portion of the V2O5 assessment, as well as a decision from EPA on whether IRIS staff must review the results of the industry-military research program before completing the assessment.

In its 2015 agenda, the IRIS program stated that it would not finalize the V2O5 assessment "at this time," saying that in discussing the agenda "it was determined that an evaluation of the potential toxicity of multiple vanadium-containing compounds, including vanadium pentoxide, was a cross-Agency high priority need."

The methylmercury assessment is also one of controversy, involving a joint advisory that EPA and the Food and Drug Administration release periodically to advise women of childbearing age on seafood in their diets. Eating seafood is considered the major, if not the only, exposure route for methylmercury, a potent neurotoxin. The IRIS assessment could be unique, because many stakeholders are calling for it to assess not only the risks of methylmercury exposure but also the health benefits of consuming fish.

EPA's Inspector General in April 2017 released a report urging the agency to EPA review whether it should reassess its 2001 methylmercury IRIS assessment, among other recommendations. -- Maria Hegstad (mehgstad@jwpnews.com)